

Applicant: Lucio Giambattista et al.

Application No: 10/824,304

Filed: April 14, 2004

Page 3

Amendments to the Specification:

Please replace original paragraph [0025] with the following rewritten paragraph:

--[0025] As described below, the safety shield 22 normally encloses the second end 38 of the needle cannula 34 as shown in FIG. 2 and the safety shield assembly 23 is enclosed by a cup-shaped cap 24 as shown in FIG. 1. The disclosed embodiment of the ~~pen-needle~~ ~~20~~ safety shield assembly 23 includes an open end 26 which may include external ribs 28 to facilitate gripping of the ~~pen-needle~~ ~~20~~ safety shield assembly 23 by the user for threaded attachment of the assembly to the pen injector as described below. As shown in FIG. 2, the pen injector 20 receives a vial shown in phantom at 30 having a pierceable closure such as a rubber septum (not shown) in the open tubular end portion 31 of the vial. The pen injector 20 further includes a needle cannula and hub assembly 32 which includes a needle cannula 34 which extends through the hub member 40 to define a first end 36 which extends into the pen injector to pierce a closure of a vial 30 or other container and a second opposed end 38 used for injection, including self-administration as described above. The hub 40 includes a tubular rim portion 42 which is preferably threadably received on the tubular end portion 44 of the pen injector 20 and a central portion 46 which receives and secures the needle cannula 34. As will be understood by those skilled in this art, the needle cannula 34 includes a lumen or small passage therethrough for transferring fluid in the vial 30 to the user for self-injection or administration by a health care worker and the tubular rim portion 42 of the hub 40 may include internal threads for threaded receipt of the hub on the externally threaded rim portion 44 of the pen injector. Needle cannula and hub assemblies of this general type

Applicant: Lucio Giambattista et al.

Application No: 10/824,304

Filed: April 14, 2004

Page 4

are well known in this art and therefore no further description of the needle cannula and hub assembly or the pen injector are required.--

Please replace original paragraph [0026] with the following rewritten paragraph:

--[0026] The safety shield system of this invention includes a generally tubular clip member 48 having a tubular body portion 50 which is received around the tubular rim portion 42 of the needle hub member 40 as shown in FIG. 2 and a plurality of laterally projecting resilient hook-shaped fingers 52 each having an outwardly facing indicating area 53 (FIG. 7). The clip member may be formed of a resilient polymeric material, such as polypropylene, such that the fingers are able to flex inwardly and resiliently flex outwardly as described below. Alternatively, the clip member 48 may be formed of a metal stamping. As shown in FIG. 2, for example, the fingers 52 are supported on a U-shaped portion 54 which further improves the resiliency of the fingers as they flex inwardly and spring outwardly. The clip member further includes a plurality of circumferentially spaced radially extending ribs 56 which prevent rotational movement of the shield 22 and guide the shield during axial movement of the shield as described below.--

Please replace original paragraph [0032] with the following rewritten paragraph:

--[0032] Following injection, the needle 38 is withdrawn from the patient and the shield 22 is simultaneously extended by the coil spring 74, such that the second end 38 of the needle cannula is never exposed. The shield is then extended axially as the needle is

Applicant: Lucio Giambattista et al.

Application No: 10/824,304

Filed: April 14, 2004

Page 5

withdrawn because the hook-shaped fingers move in the axial channel-shaped track 64 and the radial ribs 56 move through the slots or grooves 66. However, upon full extension of the shield to enclose the second end 38 of the needle, the hook-shaped fingers 52 are received through the openings 68 and the hook-shaped portion is received around the inwardly projecting tang 70, locking the shield in the extended position as shown in FIG. 7. That is, the shield 22 cannot be retracted following injection to expose the second end 38 of the needle cannula. Advantageously, the presence of the fingers 52 in the openings 68 provides a visual indicator that the safety shield 22 is locked in the extended position as shown in FIG. 7.--